UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2008-1062
Application 10/258,087
Technology Center 3700

Decided: December 22, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims directed to an endoluminal stent. The claims stand rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

"[T]he present invention relates to an implantable medical device, such as an endoluminal stent . . . having cavitated regions incorporated within the material of the device with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 13-17).

Claims 5-10 and 15-21 are pending and on appeal. Claims 1-4 and 11-14 have been canceled.

Claims 5, 8, 15, and 19 are representative of the subject matter on appeal:

5. An endoluminal stent, comprising:

a tubular member having a central lumen passing longitudinally through the tubular member and open at opposing ends of the tubular member, a luminal surface and an abluminal surface and a wall thickness defined therebetween, at least one internal cavity residing within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces on the endoluminal stent during delivery, a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member, and at least one bioactive agent disposed in the at least one internal cavity.

8. An endoluminal stent, comprising:

a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements, and a plurality of openings communicating between each of the plurality of discontinuous interior cavities and external the stent, and at least one bioactive agent disposed within the plurality of discontinuous interior cavities.

15. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of struts interconnected at a plurality of hinge regions forming a radially expandable cylindrical member, at least some of the plurality of struts being further comprised of a first regions having a first wall thickness and a second region having a second wall thickness, the first region being in proximity to one of the plurality of hinge regions and the second region being substantially isolated from each of the plurality of hinge regions;

at least one void space formed entirely within the second wall thickness of the second region, at least one of a plurality of pores communicating between the at least one void space and through the second wall thickness to at least one surface of the second region and external the endoluminal stent, and at least one bioactive agent retained within the void space and elutable through the at least one of a plurality of pores.

19. A drug eluting stent, comprising:

a plurality of metal strut members interconnected by a plurality of hinge regions, each of the plurality of strut members having an intermediate region between adjacent hinge regions, the intermediate region being subject to relatively lower stress or strain forces than the hinge regions;

a metal covering layer disposed over at least some of the plurality of strut members and covering the intermediate region of the strut members, the covering layer having an inverted generally U-shape, such that the covering layer and the intermediate region of each strut member defines an internal cavity therebetween;

a plurality of openings formed in and passing through the covering layer and communicating between the internal cavity and external the covering layer;

and at least one bioactive agent disposed in the each internal cavity, the at least one bioactive agent capable of being released from within the at least one internal cavity through the at least one of a plurality of openings.

The Examiner rejected the claims as follows:

1. Claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown (U.S. Patent 6,071,305, Jun. 6, 2000).

2. Claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang (U.S. Patent 6,758,859 B1, July 6, 2004).

3. Claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu (U.S. Patent 6,254,632 B1, July 3, 2001).

1. ANTICIPATION BY BROWN

Appellant argues the claims subject to this rejection in four groups as follows: claims 5-7; claims 8-10; claims 15 and 16; and claims 19-21. We select claims 5, 8, 15, and 19 as representative. 37 C.F.R. § 41.37(c)(1)(vii).

The Issue with Respect to Claims 5-7

Claim 5 is directed to an endoluminal stent comprising an open-ended tubular member with a luminal surface and an abluminal surface, an internal cavity within the tubular member containing a bioactive agent, and openings communicating between the cavity and the luminal and/or abluminal surfaces. There is no dispute that Brown discloses at least one embodiment, a helical stent as shown in Figures 1, 2, and 3, that meets these particular limitations of claim 5.

However, Appellant contends that the internal cavity of Brown's helical stent is not "***substantially isolated from stress or strain forces*** on the endoluminal stent during delivery," as further required by claim 5 (App. Br. 10).

The Examiner's position is that the internal cavity in Brown's helical stent is isolated from stress and strain during delivery of the stent because

"no stress/strain is applied until expansion, which occurs *after* delivery" (Ans. 10).

Thus, the issue raised by this rejection with respect to claim 5 is: Has Appellant established that the Examiner erred in concluding that the cavity in Brown's helical endoluminal stent is substantially isolated from stress and strain during delivery of the stent?

Findings of Fact

FF1 Appellant invented a "generally tubular" endoluminal stent "having cavitated regions incorporated within the material of the . . . [stent] with micropores that communicate a bioactive agent from the cavity to an area external the device" (Spec. 1: 15-17 and 26).

FF2 Claim 5 requires a stent made up of a tubular member having a central lumen where at least one internal cavity is located in a portion of the tubular member that is substantially isolated from stress or strain during delivery of the stent.

FF3 The Specification teaches that "all stents have certain structural regions that are subject to higher stress and strain conditions than other structural regions" because "stents necessarily are delivered in a reduced diametric state and are expanded or allowed to expand *in vivo* to an enlarged diametric state" so that they can serve as structural supports once in place (Spec. 5: 6-9). In other words, stents are initially biased toward a reduced state, and forced into an expanded state once in place, or they are initially biased toward an expanded state, but forced into a reduced state for delivery, and allowed to expand once in place.

FF4 According to the Specification, "it may be advantageous to position the internal cavities that retain the bioactive agents in structural regions of the stent that are subjected to relatively lower stress and strain during endoluminal delivery and deployment. Alternatively, where delivery of a bolus of a bioactive agent is desired, internal cavities may be positioned in regions that undergo large deformation during delivery and deployment thereby forcing the bioactive agent out of the internal cavity under the positive pressure exerted by the deformation" (Spec. 5: 9-15).

FF5 Further according to the Specification, internal cavities may "reside within regions of the device . . . that are substantially non-load bearing" (Spec. 12: 6-7). Alternatively, "regions . . . that are deformed or that are load bearing may include . . . internal cavities within their wall thickness and provide for elution of a bioactive agent retained within the internal cavity positioned at the load bearing region under the influence of a positive motivating pressure exerted on the bioactive agent by deformation or load stress transferred by the device geometry to the internal cavity and to the bioactive agent" (Spec. 12: 10-15).

FF6 The Specification does not explicitly identify regions that are "substantially isolated from stress or strain forces on the endoluminal stent during delivery" (as required by claim 5), but it can be inferred from the passages quoted in FF4 and FF5 that regions of the stent that undergo "large deformation" during delivery and deployment, and/or load bearing regions, are subject to higher stress and strain conditions than other structural regions, while regions that do not undergo "large deformation," or are non-load bearing, are regions that are subject to lower stress and strain.

FF7 The Specification teaches that "hinge regions . . . are load bearing regions of the stent" (Spec. 12: 8-9), thus, hinge regions are regions that are subject to higher stress and strain during delivery and deployment.

FF8 An example of a stent with internal cavities located in regions substantially isolated from stress and strain is depicted in Figure 11 of the Specification, reproduced immediately below:

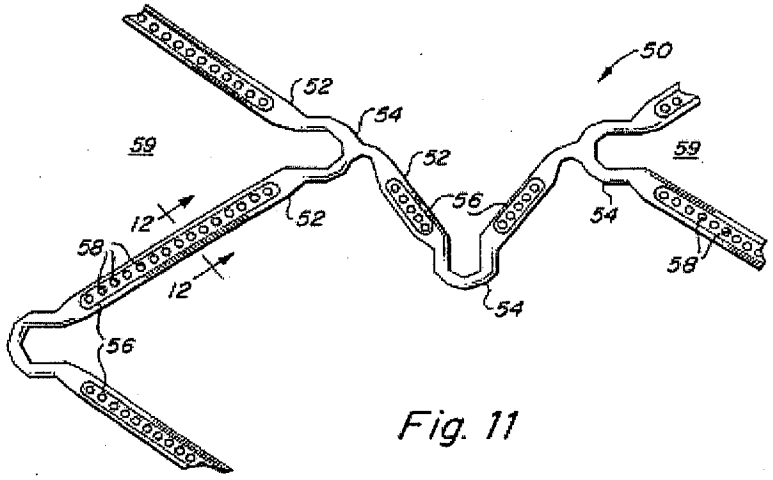

Fig. 11

Figure 11 shows a portion of an expandable stent in which "the plurality of hinge regions 54 are devoid of internal cavities 56 because they are load bearing regions of the stent" (Spec. 12: 8-9).

FF9 Brown describes a drug delivery stent **11**, an example of which is illustrated in Figures 1 and 2, reproduced immediately below:

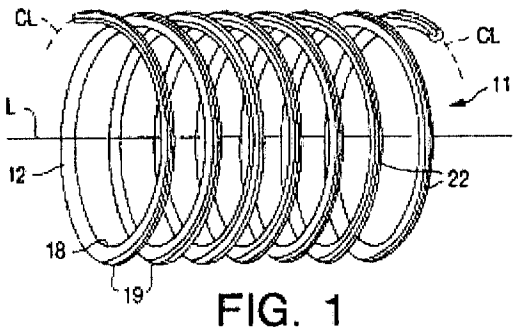

FIG. 1

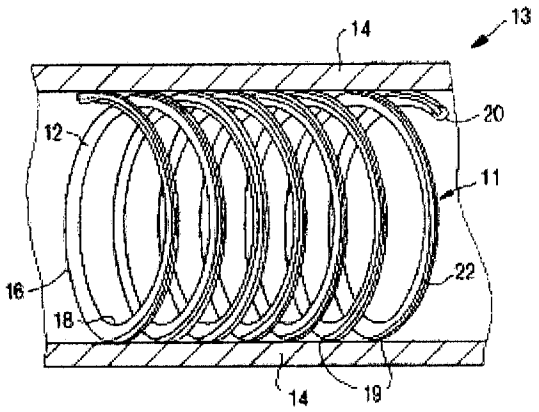

FIG. 2

Figure 1 is a perspective view of a stent **11** "formed from an elongated or tubular member **12** . . . [which] is in the shape of a coil or helix, and is expanded within a body lumen" after delivery (Brown, col. 5, ll. 39-42). Figure **2** is a cross-sectional view of a body lumen and a perspective view of stent **11** in place in the lumen (Brown, col. 3, ll. 63-65).

FF10 "The tubular or elongated member **12** of [Brown's] directional drug delivery stent **11** . . . is formed with an interior or cavity **20**, which . . . is a concave groove within the interior of the elongated member **12**" (Brown, col. 5, ll. 45-50). "[C]avity **20** contain[s] a biologically active agent for directional application" (Brown, col. 4, ll. 62-63).

FF11 "Although the cavity **20** illustrated in [Brown's] Fig. **2** is a concave groove, the interior may be other configurations and need not extend the entire length of the elongated or tubular member **12**" (Brown, col. 5, ll. 51-54). In addition, "[a]lthough the slit shaped opening **22** is illustrated, any number of fluid opening configurations may be fashioned. For example, a series or plurality of holes, grooves, small indentations, and intermittent recessions could all be fluid openings and delivery means for

directionally delivering the biologically active agent" (Brown, col. 6, ll. 13-17).

FF12 An embodiment of Brown's helical stent with the cavity on the luminal surface of the elongated, tubular member is shown in Figure **3**, reproduced immediately below:

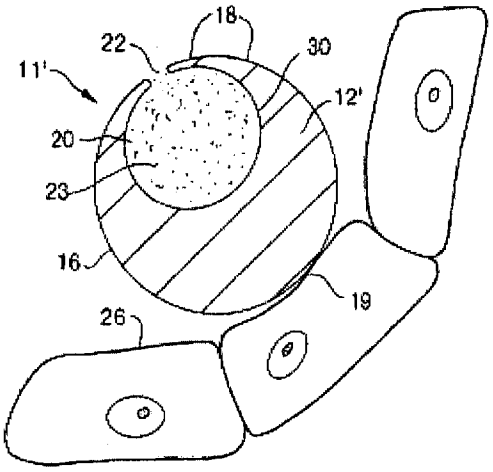

FIG. 3

Brown's Figure **3** is a "cross-sectional view of the elongated member **12′** of the stent **11′"** (Brown, col. 8, ll. 5-6), in which cavity **20** and opening **22** extend along the luminal surface of elongated, tubular member **12′**. That is, both the cavity and the opening are on the inside surface of the stent.

FF13 Brown's helical stent "has an initial diameter at which it is inserted into a body lumen, and an expanded final diameter" once in place (Brown, col. 7, ll. 26-28).

Analysis and Conclusion of Law, Claims 5-7

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

According to the Examiner, the cavity in Brown's helical stent "resid[es] within the wall thickness in portions of the tubular member that are substantially isolated from stress or strain forces . . . during delivery" (Ans. 4), at least in part because Brown's stent is delivered in an un-expanded state, and is subjected to minimal stress and strain until expansion, "which occurs *after* delivery" (Ans. 10).

Appellant contends that "Brown discloses a helical coil stent structure, where all the regions would undergo substantial stress and strain forces during delivery and deployment . . . Consequently, Brown does not contain the element recited in Claim 5 of an internal cavity substantially isolated from stress or strain forces" (App. Br. 11).

Appellant's argument is not persuasive. The Specification identifies hinge regions as regions of relatively high stress and strain during delivery and deployment (FF5, 6, 7). Brown's helical stent has no hinge regions (FF9). Nevertheless, even if we accept for the sake of argument that "all of the regions" in Brown's helical stent would undergo stress and strain at some point during delivery and deployment, the Specification distinguishes between delivery and deployment (FF3), and claim 5 merely requires isolation from stress and strain during *delivery* (FF2). Brown's stent is delivered to a location in a vessel in an initial, unexpanded state, and is expanded to its final diameter (i.e., deployed) *after* delivery (FF13).

Appellant has not established that Brown's helical stent is either load-bearing or deformed during delivery, as opposed to deployment (i.e., expansion). Therefore, Appellant has not shown that the Examiner erred in

concluding that "minimal stress/strain" is placed on the cavity of Brown's stent during delivery (Ans. 10).

The Issue with Respect to Claims 8-10

Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls, with a plurality of discontinuous interior cavities disposed within at least some of the structural elements.

The Examiner asserts that at least one of Brown's embodiments, an expandable "tube-type" stent as shown in Figure **18**, meets all of the limitations of claim 8, including the requirement for a plurality of discontinuous interior cavities.

Appellant contends that "Brown does not disclose 'a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements', as recited in Claim 8" (App. Br. 11).

Thus, the issue raised by this rejection with respect to claim 8 is: Has Appellant established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous?

Additional Findings of Fact

FF14 Claim 8 is directed to an endoluminal stent comprising a cylindrical member comprised of a plurality of interconnected structural elements defining walls of the cylindrical member, with "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements," a plurality of openings communicating between each of the cavities and the outside of the stent, and at least one bioactive agent disposed within the cavities.

FF15 According to the Specification, "both the plurality of internal cavities 12 and the plurality of pores [i.e., openings] 14 may be positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body 20" (Spec. 7: 21-23). In addition, "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25, which completely subtends the internal cavity 12, divid[ing] it into discrete discontinuous internal cavities 12" (Spec. 7: 23-26).

FF16 Brown describes a number of stent configurations other than the helical stent discussed above, such as "expandable tube stents, roving wire stents, and wire mesh stents. Thus the elongated member **12** may be the filaments or fibers which form a mesh stent" (Brown, col. 7, ll. 37-39).

FF17 Brown's Figures 17 and 18 show an expandable tube-type stent before and after expansion, respectively. Figures 17 and 18 are reproduced immediately below:

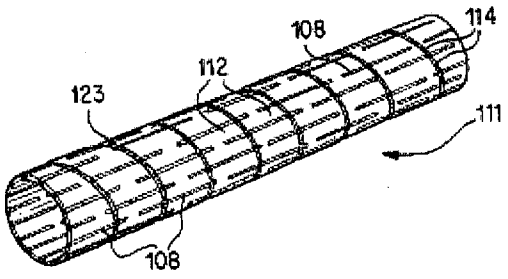

FIG. 17

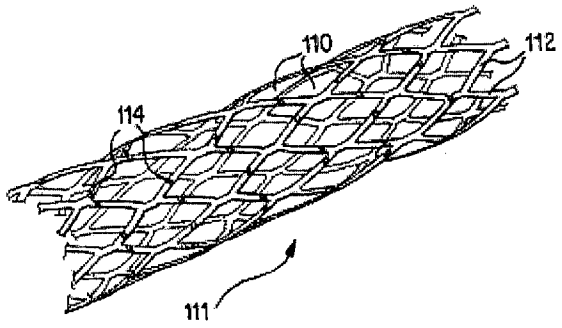

FIG. 18

Figure 17 "illustrates an example of the aforementioned expandable tube-type stent **111** . . . [Figure 18] illustrates the stent . . . in an expanded state" (Brown, col. 11, ll. 63-64).

FF18 Brown's "tube-type stent **111** is manufactured by cutting an elongated tubular member into tubular sections" (Brown, col. 12, ll. 1-2). Then, "[a] recessed active agent receiving . . . groove **120** is formed in the exterior surface **104** of the tube **102**. The groove **120** . . . is preferably a continuous helical or coiling groove extending around the tube **102** . . . the groove **120** need not be continuous" (Brown, col. 12, ll. 14-20). "Once the . . . groove **120** has been filled with active agent **123** . . . a plurality of . . . slots **108** are formed in the tube **102** . . . and extend completely through the tubular member . . . wall thickness" (Brown, col. 12, ll. 61-67).

FF19 Brown teaches that "one function of the slots is to permit the stent **111** to be expanded" (Brown, col. 13, ll. 9-10). "Because the preferred slots **108** extend longitudinally along the tube **102** and the . . . groove **120** extends helically around the tubular member, *the slots intersect the groove to define a plurality of spaced apart groove portions* **114**, each containing active agent" (Brown, col. 13, ll. 14-19 (emphasis added)). In other words, "[w]hen the tube is expanded, the tubular material between the slots **108**

forms the angled fibers or elongated members **112**, and the slots **108** form the interstitial openings **110** . . . . At least some of the elongated members **112** contain groove portions **114** or cavities in which the active agent is located" (Brown, col. 13, ll. 23-29).

FF20 Thus, Brown describes a stent with spaced apart, i.e., discontinuous, interior cavities.

Analysis and Conclusion of Law, Claims 8-10

Appellant contends that "Brown's 'plurality of cavities' in Fig. 18 does not make them discontinuous. For Claim 8, a discontinuous cavity is a *single* cavity marked by a break or interruption" (Reply Br. 9). Appellant concedes that Brown "disclose[s] a number of cavities per filament," but contends that "'Discontinuous' modifies cavity, thereby making 'discontinuous interior cavities' requiring that the cavity itself . . . be discontinuous, not the plurality of cavities to be discontinuous" (*id.*).

Appellant's argument is not persuasive. According to the Specification, the cavities may be "discontinuous" in two ways: (1) they are "positioned to be discontinuous and in different circumferential or different longitudinal regions of the tubular body" (FF15), or (2), "[w]ithin a single one of the plurality of interconnected structural elements 21, the internal cavities 12 may be separated by a separation member 25 . . . [dividing the cavities] into discrete discontinuous internal cavities 12" (FF15).

Claim 8 is not limited to the second embodiment described in the Specification where a single cavity is divided into discrete, discontinuous portions (FF14). Claim 8 merely requires "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of

structural elements" (FF14). Brown describes spaced apart grooves (i.e., cavities) disposed within different regions of the stent (FF19, 20), thereby meeting the requirement of claim 8 for discontinuous interior cavities.

Appellant has not established that the Examiner erred in concluding that the cavities in Brown's tube-type stent are discontinuous.

The Issue with Respect to Claims 15 and 16

Claim 15 is directed to a radially expandable, cylindrical endoluminal stent comprising a plurality of struts interconnected at a plurality of hinge regions. At least some of the struts are comprised of a first region "having a first wall thickness" in proximity to one of the plurality of hinge regions, and a second region "having a second wall thickness" substantially isolated from each of the plurality of hinge regions, with at least one void space formed entirely within the second wall thickness of the second region (claim 15).

Appellant contends that Brown only discloses stents with struts comprising a single wall thickness, and that Brown does not disclose "'a second region being substantially isolated from each of the plurality of hinge regions; [with] at least one void space formed entirely within the second wall thickness of the second region'" (App. Br. 13), and therefore fails to meet all the limitations of claim 15.

The Examiner asserts that claim 15 does not require the first and second thicknesses to be "two different thicknesses" (Ans. 11), nor does the claim "*exclude* . . . [void spaces] from being on the first region of the stent" (*id.*).

The issue raised by this rejection with respect to claim 15 is: Has the Examiner established that Brown anticipates the invention of claim 15 based on the broadest reasonable interpretation of the claim consistent with Appellant's Specification?

Additional Findings of Fact

FF21 The Examiner finds that Brown's expandable "tube-type" stent, shown in Figure **18**, meets all the limitations of claims 15 and 16, including the requirement for struts comprising first and second wall thicknesses, and the requirement for at least one void space formed entirely within the second wall thickness of the second region, where the second region is substantially isolated from each of the hinge regions (Ans. 5).

FF22 Appellant's claim 17, which depends from claim 15 and is not subject to this rejection, stipulates that "the second wall thickness is greater than the first wall thickness," further limiting the first and second wall thicknesses to two different wall thicknesses. Thus, claim 15 does not require the first and second wall thicknesses to be two different wall thicknesses.

FF23 According to Appellant's Specification, cavities may be located in both load bearing regions (e.g., hinge regions) and non-load bearing regions (e.g., regions isolated from hinge regions), in order to achieve the desired rate and timing of elution of the active agent(s) (Spec. 12: 18).

FF24 Claim 15 requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," but the claim uses the open transitional term "comprising," and is therefore not

limited to a stent with voids located *exclusively* in regions isolated from the hinge regions.

FF25 The expandable tube-type stent shown in Brown's Figures 17 and 18 (reproduced above) has "[a] recessed active agent receiving portion or groove **120** . . . formed in the exterior surface of the tube **102**" (Brown, col. 12, ll. 14-15). "Once the recessed active agent receiving portion or groove **120** has been filled with active agent **123** . . . a plurality of perforations, slits, or slots **108** are formed in the exterior surface **104** of the tube **102**, and extend completely through the tubular member thickness" (Brown, col. 12, ll. 61-67). Slots **108** "intersect the groove to define a plurality of spaced apart groove portions **114**, each containing the active agent" (Brown, col. 13, ll. 17-19).

FF26 Figure 18 (reproduced above) shows several spaced apart groove portions or recessed active agent receiving portions **114** that are formed entirely within regions that are substantially isolated from the hinge regions.

Analysis and Conclusion of Law, Claims 15 and 16

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). However, the claims are not to be confined to the embodiments found in the Specification, and it is improper to import limitations from the Specification into the claims. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007).

Appellant contends that Brown does not disclose "two different wall thicknesses" as required by claim 15 (App. Br. 13).

This argument is not persuasive. Claim 15 does not require that the first and second wall thicknesses are different (as opposed to narrower dependent claim 17, which does) (FF22).

Appellant contends that "Brown's Fig. 18 . . . clearly shows groove portions 114 [that] intersect with or are immediately adjacent to . . . hinge regions of the stent struts 112 . . . Thus, it cannot be said that the groove portions 114 are ***substantially isolated from each*** [and every] of the plurality of hinge regions, as claimed" (App. Br. 13, 14).

This argument is not persuasive. Claim 15 merely requires "at least one void space formed entirely within the second wall thickness of the second region" which is "substantially isolated from each of the plurality of hinge regions," and the open language of the claim does not preclude voids located in the hinge regions as well (FF24) Moreover, this interpretation of the claim is consistent with the Specification, which teaches that cavities (i.e. void spaces) may be located in both load bearing regions (e.g. hinge regions), as well as non-load bearing regions, depending on the desired elution profile (FF23).

Finally, Appellant argues that groove space 114 "is not a 'void space formed entirely within' a second wall thickness . . . [because] the groove

portions 114 open not only at their upper opening, but the end openings defined in the stent struts become exposed to the exterior of the wall thickness of elongated members 112 . . . [and] the open surface of the groove 123 changes as the stent is radially expanded" (App. Br. 14).

This argument is not persuasive. Brown's grooves are located in the walls of the struts. Appellant has not identified anything in the Specification which supports his restrictive definition of "a void space entirely within" the wall thickness.

The Examiner has established that Brown anticipates the stent of claim 15, based on a reasonable interpretation of the claim consistent with the Appellant's Specification.

The Issue with Respect to Claims 19-21

Claim 19 is directed in part to a drug eluting stent comprising a plurality of metal strut members interconnected by a plurality of hinge regions. The claim requires a generally U-shaped metal covering layer with a plurality of openings formed in it, disposed over the intermediate regions between adjacent hinges of at least some of the struts, defining an internal cavity therebetween.

The Examiner asserts that the requirement for a U-shaped metal covering is met by "portion 19" of Brown's drug eluting stent (Ans. 6).

Appellant contends, at least in part, that "portion 19 is a portion of the circumference of the elongated member . . . [and] is not a layer as to anticipate Claim 19's metal covering layer" (App. Br. 16).

The issue raised by this rejection with respect to claim 19 is: Has the Examiner provided an adequate factual basis to support her conclusion that Brown discloses a stent with a U-shaped metal covering?

Additional Findings of Fact

FF27 The Examiner asserts that the required U-shaped "metal covering layer may be considered to be [the] top layer of the stent 19, . . . [as shown in] fig. 4, 6 for example" (Ans. 6).

FF28 Brown's Figure 4 is reproduced immediately below:

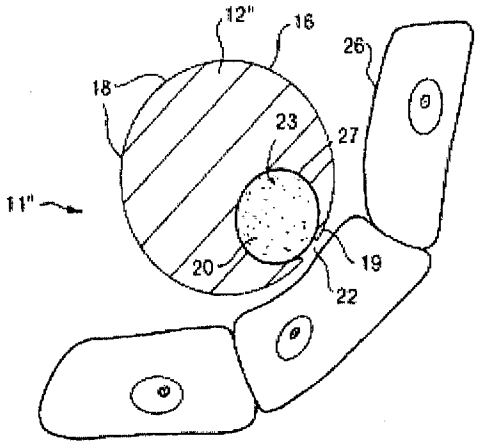

FIG. 4

Figure 4 is a cross-sectional view of the elongated member **12"** of a stent **11"** which "directionally delivers the biologically active agent **23** from the cavity **20** and through the slit opening **22**, which is located at the support portion **19** of the outer surface **16**, such that the biologically active agent is delivered to the body lumen wall **26**" (Brown, col. 8, ll. 55-60).

FF29 Elongated member **12"** can form the struts of a mesh stent (FF21), however, support portion **19** is an integral part of elongated member **12"**, and is not a U-shaped metal layer covering portion of the elongated member/strut **12"**.

Analysis and conclusion of Law, Claims 19-21

> The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because *it* may *doubt* that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings *are* so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion . . .

In re Warner, 379 F.2d 1011, 1017 (CCPA 1967) (emphasis in original). *Warner* concerned the factual basis of an obviousness rejection, but its central premise is equally appropriate here.

Even if we accept, for the sake of argument, that Brown's support portion **19**, which is an integral part of elongated member/strut **12"** (FF29), is a "covering layer" forming a cavity between the strut and support portion **19**, the Examiner has not pointed to anything in Brown which shows that it is U-shaped.

Thus, the Examiner has not provided the factual basis necessary to support her conclusion that Brown discloses a stent with a U-shaped metal covering.

Decision with Respect to Anticipation by Brown

We affirm the rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Brown with respect to claims 5-10, 15, and 16, but reverse the rejection with respect to claims 19-21.

2. ANTICIPATION BY DANG

The Examiner rejected claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

The Issue

The Examiner's position is that Dang describes an endoluminal stent comprising a tubular member that meets all of the limitations of claims 5-10 and 15-18, including the requirement for "a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface, abluminal surface, proximal end or distal end of the tubular member" (claim 5); the requirement for "a plurality of openings communicating between each of the . . . interior cavities and external the stent" (claim 8); and the requirement for "a plurality of pores communicating between the at least one void space [formed entirely within the wall of the stent] . . . and external the endoluminal stent" (claim 15).

Appellant contends in part that Dang does not teach or disclose a "***plurality of openings***" or a "***plurality of pores***" communicating between any single internal cavity or void space in the wall of the stent and the exterior of the stent (App. Br. 21, 23), as required by all the claims subject to this rejection. In other words, Appellant contends that Dang discloses only a "***single opening***" per cavity or void space (*id.* at 21).

Thus, the issue raised by this rejection with respect to claims 5-10 and 15-18 is: Has the Examiner provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and the surface of the stent?

Findings of Fact

FF30 All of the claims subject to rejection over Dang require a plurality of openings or pores communicating between a single internal cavity or void, residing or disposed within the wall thickness or structural elements of the stent, and the exterior of the stent. That is, all of the claims require more than one opening or pore per cavity or void. Moreover, the luminal surface of the stent is not a cavity or void residing or disposed within a wall thickness or structural element of the stent.

FF31 Dang describes a cylindrical or tubular expandable "prosthesis, one example of which includes a stent . . . The outer surface of the prosthesis is capable of contacting an inner lumen surface of a passageway. In addition, the body structure of the prosthesis has one or more elements having a width and a thickness. The width of the element(s) is variable from a nominal or conventional width to an increased width" (Dang, col. 2, ll. 41-51).

FF32 Dang's "variable width prosthesis includes one or more depots formed on the elements of the prosthesis. The depots have an open end, a closed end, a diameter and a depth that is less than the thickness of the body structure of the prosthesis. In general, the depots are formed at the increased width sections of the elements" (Dang, col. 2, ll. 52-58).

FF33 "The depots **30** are formed to carry . . . therapeutic substances" (Dang, col. 5, ll. 10-11), and the depth, diameter, and quantity of the depots, as well as their location on the elements **22** of the stent, varies according to intended usage and application (Dang, col. 6, ll. 24-27; col. 8, ll. 29-30).

FF 34 Dang's Figures **5***a* and **5***b*, reproduced immediately below, show cross-sectional and top views of "a plurality of depots on a surface portion" of a stent (Dang, col. 3, ll. 20-23):

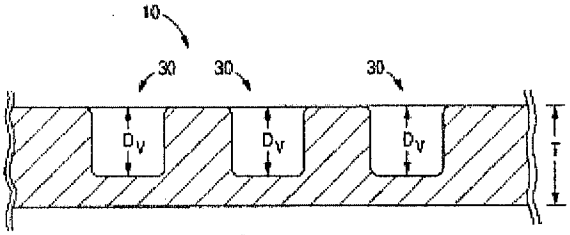

Figure 5a

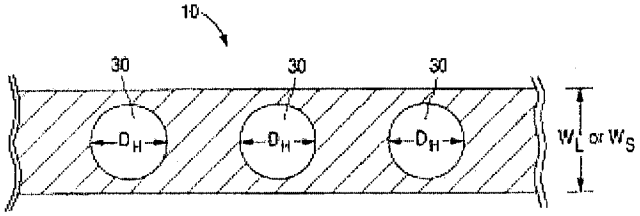

Figure 5b

Figures **5***a* and **5***b* illustrate cross-sectional and top views of individual depots **30** for therapeutic substances.

FF35 While Dang's stent has a plurality of depots, and "depot configurations . . . can include . . . tear-drop shaped, cubic shaped, spherically shaped, and other configurations and shapes" (Dang, col. 6, ll. 60-63), none of the depots described by Dang has more than one opening per depot.

Analysis and Conclusion of Law

All of the claims subject to this rejection require a plurality of openings or pores per cavity or void (FF30), not merely a plurality of openings or pores in the stent as a whole.

The Examiner asserts that Dang describes a stent with "a plurality of openings (open end is considered an 'opening' . . . [and] the cavities may be

any shape, including shapes such as tear drop, wherein the opening is smaller that the cavity . . .) communicating between the at least one internal cavity (30) and at least one of the luminal surface, abluminal surface, proximal end, or distal end of the tubular member (fig. 5a)" (Ans. 7).

We agree with Appellant that "no single depot 30 disclosed in the Dang reference contains a 'plurality of openings', i.e., more than one opening . . . [and] [a] tear drop opening still only contains a ***single opening***" (App. Br. 21).

Thus, the Examiner has not provided an adequate factual basis to support her conclusion that Dang discloses a stent with a plurality of openings or pores communicating between an internal cavity or void and an exterior surface of the stent.

Decision

We reverse the rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang.

3. ANTICIPATION BY WU

The Examiner rejected claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

The Issues

Appellant contends, among other things, that "Wu does not disclose 'a plurality of openings communicating between the at least one internal cavity and at least one of the luminal surface'" as required by claims 5-7 (App. Br. 27), or "a plurality of discontinuous interior cavities disposed completely within at least some of the plurality of structural elements" (*id.* at 28) with "a plurality of openings communicating with an internal cavity and external the

stent" as required by claims 8-10 (*id.* at 29); or "a 'void space formed entirely within the second wall thickness' of a strut region" as required by claim 15 (*id.*).

The Examiner's position is that "Wu discloses a stent . . . comprising a structural member (104, 102) and cover member (420) and a cavity (area occupied by agent 410 . . .) therebetween, and a plurality of openings (openings in porous polymer cover 420) passing through the cover member" (Ans. 9).

The issues raised by this rejection are: Has the Examiner provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent, and that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent, with a plurality of openings communicating between the cavities or void spaces and the exterior of the stent?

Additional Findings of Fact

FF36 Wu describes "protruding structures . . . [on] the surface of a stent . . . [which] can be used with covered stents . . . to engage and secure the cover, . . . to keep glue in place on the stent when attaching the covering. The protruding structures can also be used to deliver therapeutic substances from the stent directly to the lumen wall" (Wu, col. 2, ll. 53-62).

FF37 "An exemplary protruding structure includes a depression region having a bottom surface that is fully or partially surrounded by a protruding lip . . . [that] is higher than the bottom surface relative to the surface of the stent" (Wu, col. 2, l. 64 to col. 3, l. 2).

FF38 Wu's Figure **2**B is reproduced immediately below:

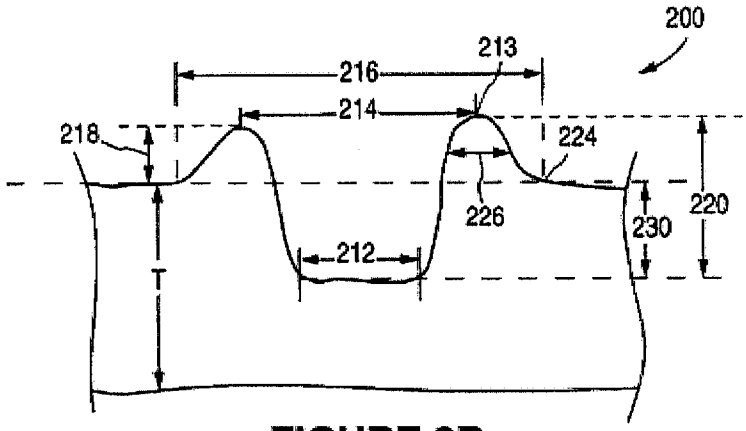

FIGURE 2B

Figure **2**B "is a cross-sectional side view of a portion of a stent strut with a crater that has a bottom surface recessed beneath the stent surface" (Wu, col. 3, ll. 46-48).

FF39 Wu's Figure **4**A is reproduced immediately below:

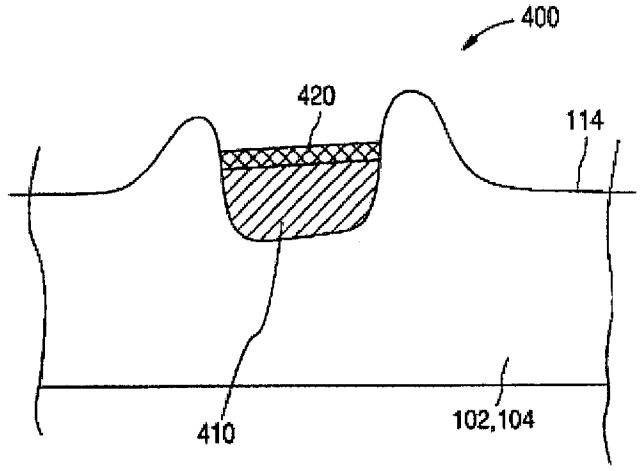

FIGURE 4A

Figure **4**A is a cross-sectional side view of a "protruding structure[ ] that contain[s] a therapeutic substance . . . covered by a polymeric layer" (Wu, col. 3, ll. 63-65).

FF40 The Examiner describes polymeric layer **420** as "porous" (Ans. 9), but does not point to anything in Wu which indicates that the polymer actually is porous. Wu merely describes the "[p]olymeric materials that can be used for layer **420**, **430** . . . [as] either bioabsorbable or biostable" polymers which "are gradually absorbed or eliminated from the body by hydrolysis, metabolic process, bulk or surface erosion" (Wu, col. 6, ll. 37-43).

FF41 The Examiner's assertion that Wu's polymer layer **420** meets the claims' requirement for a plurality of openings per cavity or void space is not supported by Wu's description of the polymer layer.

Analysis and Conclusion of Law

While Wu's stent has a plurality of cratered structures, the structures, including the craters, protrude at least partially from the surface of the stent (FF 36-39), thus none of the craters (i.e., cavities or voids) is "disposed completely within" or "formed entirely within" a structural element or strut (as required by claims 8-10 and 15). Moreover, none of the protruding structures has more than one opening per crater (as required by claims 5-10 and 15) (FF40, 41).

The Examiner has not provided an adequate factual basis to support her conclusion that Wu discloses a stent with a plurality of openings or pores communicating between an internal cavity and the surface of the stent as required by claims 5-7, or that Wu describes a stent with cavities or void spaces formed entirely within the structural elements or struts of the stent (as required by claims 8-10 and 15), with a plurality of openings communicating

between the cavities or void spaces and the exterior of the stent (as required by claims 5-10 and 15).

Decision

We reverse the rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu.

SUMMARY

The rejection of claims 5-10, 15, 16, and 19-21 under 35 U.S.C. § 102(e) as anticipated by Brown is AFFIRMED with respect to claims 5-10, 15, and 16, but REVERSED with respect to claims 19-21.

The rejection of claims 5-10 and 15-18 under 35 U.S.C. § 102(e) as anticipated by Dang is REVERSED.

The rejection of claims 5-10 and 15 under 35 U.S.C. § 102(e) as anticipated by Wu is REVERSED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

Ssc:

David G. Rosenbaum
Rosenbaum & Associates, P.C.
Suite #380
650 Dundee Road
Northbrook, IL 60062